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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,193	12/07/2005	Geoffrey R. Hill	SPRUS1140.US (064206-0701	9978

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

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03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,193	HILL ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-20 and 22-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18-20,22-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

2. Reference A3 on the IDS of 2/6/06 was not considered because the journal name was incorrect. Reference A13 on the IDS of 2/6/06 was not considered because portions of the reference were illegible.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7,9-16,18-20,22-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed method.

The claims encompass use of cpn10 from any animal species or unknown mutants/alleles of human cpn10. It appears that the only cpn10 proteins of human or murine origin were known in the art. Thus, whilst only two specific types of cpn10 were known in the art, the claims encompass use of cpn10 derived from any animal species or unknown mutants/alleles/derivatives of human cpn10. The claims also recite use of cpn10 derivatives wherein said derivative encompass a vast collection of unknown molecules. The identity of unknown mutants/alleles/derivatives with cpn10 activity is unpredictable. Thus, the written description provided in the specification is not

commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli
Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

5. Regarding the application of prior art, the foreign priority document does not disclose the scope of the claimed inventions.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 20, 22-26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Coates et al. (WO 02/40038).
Coates et al. disclose a pharmaceutical composition comprising an effective amount of cpn10 and a diluent (see pages 9-10). Coates et al. disclose that the compositon can also contain an immunosuppressive drug such as a steroid (aka glucocorticosteroids) or (see page 9, last paragraph). Coates et al. disclose in vivo administration of said cpn10 (see claim 9) to humans (see page 13) wherein said agent stimulates IL-10 production (see claims 10/12). Coates et al. also disclose that cpn10 stimulates IL-10 production in treated cells (see claims 10-12).

8. Claims 16,18-20,22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Morton et al. (US 6,117,421).
Morton et al. disclose in vivo treatment of humans with cpn10 (see claims 8-10) wherein it is an inherent property of said treatment that said treatment has the functional effect of claims 16/20 because said method uses the same ingredient in a therapeutically effective amount. The cpn10 is administered in vivo with a diluent (see column 15, last paragraph).

9. Claims 16,18,20,22,24,29 are rejected under 35 U.S.C. 102(a) as being anticipated by Somodevilla-Torres et al.

Somodevilla-Torres et al. disclose in vivo treatment of a mammal with the protein recited in claim 29 (aka rAla1-101) wherein it is an inherent property of said treatment that said treatment has the functional effect of claims 16/20 because said method uses the same ingredient in a therapeutically effective amount (see pages 277,279-280,284). The cpn10 is administered in vivo with a diluent (aka vehicle, see page 279).

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-7,9-16,18-20,22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton et al. (US 6,117,421) in view of Kimura et al.
Morton et al. disclose in vivo treatment of humans with cpn10 (see claims 8-10) wherein said treatment has the functional effect of claims 16/20 because said method uses the same ingredient in a therapeutically effective amount. The cpn10 is administered in vivo with a diluent (see column 15, last paragraph). Morton et al. do not disclose cpn10 treatment of GVHD using the steps/compositions recited in the claims. Morton et al. disclose that cpn10 can be used to promote immunosuppression in a subject to treat graft rejection (see column 6, column 18 and claim 8). The art recognizes that GVHD is caused by transplantation of grafts containing donor lymphocytes including bone marrow (see Kimura et al., page 215, first column). Kimura et al. teach that GVHD can

be treated by administering immunosuppressive agents to both the recipient and bone marrow donor (see abstract). The optimal administration schedule for cpn10 treatment would be determined by routine experimentation. The optimal dosage would be determined by routine experimentation wherein Morton et al. disclose a dosage of cpn10 for immunosuppression that overlaps that recited in the claims (see column 19). The methods encompass treatment of humans. The use of cyclosporin and steroids for treatment of graft rejection was well known in the art (for example see Kimura et al.. pages 214-215). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Morton et al. disclose that cpn10 can be used to promote immunosuppression in a subject to treat graft rejection whilst Kimura et al. teach that GVHD can be treated by administering immunosuppressive agents to both the recipient and bone marrow donor and the use of cyclosporin and steroids for treatment of graft rejection was well known in the art. One of ordinary skill in the art would have been motivated to do the aformentioned because Morton et al. disclose that cpn10 can be used to promote immunosuppression in a subject to treat graft rejection whilst Kimura et al. teach that GVHD can be treated by administering immunosuppressive agents to both the recipient and bone marrow donor and the use of cyclosporin and steroids for treatment of graft rejection was well known in the art. In addition in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

12. Claims 8,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton et al. (US 6,117,421) in view of Kimura et al. as applied to claims 1-7,9-16,18-20,22-28 above, and further in view of Somodevilla-Torres et al.

The previous rejection renders obvious the claimed inventions except for use of the particular form of cpn10 recited in the claims. Somodevilla et al. teach in vivo treatment of a mammal with the cpn10 protein recited in claim 29 (aka rAla1-101). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was

made to have created the claimed invention because the previous rejection renders obvious the claimed invention except for use of the particular form of cpn10 recited in the claims whilst Somodevilla et al. in vivo treatment of a mammal with the cpn10 protein recited in claim 29 (aka rAla1-101). In addition in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

13. Claim 25 is objected to because of the following informalities. "In claim 25 "immuunosuppressive" should be "immunosuppressive", Appropriate correction is required.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron, Ph.D./
Primary Examiner, Art Unit 1644